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Appendix A

FDA Has No Authority Under the Federal Food, Drug, and Cosmetic Act to Require Manufacturers of Food and Cosmetics to Disclose to FDA Inspectors Company Records Relating to Exported Products

This Appendix demonstrates that FDA has no statutory authority to require Agency inspection of company records relating to compliance of exported food and cosmetics with Section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

I. THE RECORDS INSPECTION PROVISION OF THE REGULATION EXCEEDS FDA'S STATUTORY AUTHORITY.

A. Section 704 Of the FD&C Act Does Not Authorize FDA To Inspect The Records of Food and Cosmetic Manufacturers.

The inspection authority granted to FDA by the FD&C Act does not extend to the mandatory examination of records maintained by food and cosmetic manufacturers. Under Section 704(a), the Agency's authority to inspect the factory, warehouse, establishment, or vehicle of a food or cosmetic manufacturer is limited to "all pertinent equipment, finished and unfinished materials, containers, and labeling therein." In particular, this authority does *not* provide for the review of records. Indeed, each time Congress has determined that records inspection is warranted -- for prescription drugs,[1] restricted devices, [2] infant formula[3], and nonprescription drugs[4] -- it specifically amended Section 704(a) to provide FDA with this expanded inspection authority. If FDA already possessed the authority to inspect records under the FD&C Act, no amendment of the Act would have been required and the records inspection provisions relating to prescription drugs, restricted devices, infant formula, and nonprescription drugs, would be superfluous.

The Agency has sought records inspection authority for food and cosmetics establishments from Congress on several occasions. These efforts have been vigorously opposed by industry because of the serious legal and constitutional issues raised and because FDA has adequate enforcement powers without records inspection. Through the testimony of both the Agency and industry representatives, Congress has been able to consider the competing interests

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1 76 Stat. 780 (1962).

2 90 Stat. 539 (1976).

3 94 Stat. 1190 (1980).

4 111 Stat. 2296 (1997).

involved, and has determined repeatedly that records inspection authority is not warranted for food and cosmetics products.

B. The Inspection Of Records Is Not Authorized Under Sections 701(a) and (b) Of the FD&C Act.

Section 701(a) of the FD&C Act provides that the Agency has the authority to promulgate regulations for the efficient enforcement of the FD&C Act generally and Section 701(b) grants this authority jointly to the Secretary of the Treasury and FDA with respect specifically to Section 801 of the FD&C Act. After 50 years of acknowledging its lack of authority under Section 704 to inspect the records of food and cosmetic manufacturers, FDA cannot now assert that it possesses this authority under Sections 701(a) and 701(b). [5] Sections 701(a) and 701(b) only authorize FDA to issue regulations implementing other substantive provisions of the Act. They do not permit FDA to contravene congressional intent by imposing regulatory requirements exceeding the limited inspection authority provided under the statute.[6] Therefore, Sections 701(a) and 701(b) only helps if another section of the Act authorizes FDA access to company records. None does.

For example, Congress has specifically provided, and the Agency has exercised, limited records inspection authority under Section 404 of the FD&C Act,[7] and the food industry has not disputed this authority. Section 404 provides FDA with explicit emergency permit authority over food that "may, by reason of contamination with microorganisms... be injurious to health." Pursuant to Section 404, FDA has promulgated regulations to assure adequate processing of acidified and low acid canned food in order to prevent contamination with pathogens.[8] These specialized provisions are warranted in light of the extreme toxicity of botulism, which could result from the improper processing of these products.

Under Section 404(c), Congress explicitly granted FDA the authority to inspect any food establishment "for the purpose of ascertaining whether or not the conditions of the permit are being complied with." This authority is in addition to the general inspection authority under Section 704, and thus was clearly intended by Congress to extend beyond the limited power provided to FDA for all other types of food inspection. In the context of this specific and broader statutory grant of authority to inspect for compliance with an emergency permit, it is reasonable to include those records that bear directly on such compliance. This broader records inspection authority under Section 404(c) is limited to emergency permits, however, and stands in stark contrast to the narrower inspection authority under Section 704(a). Section 404(c) has no bearing on FDA's authority to conduct records inspections in other circumstances.

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5 Under no circumstances can these regulations be regarded as promulgated under Section 701(b), because they were not issued jointly by the Department of the Treasury and FDA as required under that provision.

6 *National Confectioners Association v. Califano*, 569 F. 2d 690, 695 (D.C. Cir. 1978).

7 21 C.F.R. §§ 108.25(g), 108.35(h).

8 21 C.F.R. Parts 113 and 114.

II. FDA HAS REPEATEDLY ACKNOWLEDGED THAT IT LACKS THE AUTHORITY TO INSPECT FOOD AND COSMETIC RECORDS.

Repeatedly throughout the history of the FD&C Act, FDA has acknowledged the limitations on its authority which prohibit the Agency from requiring food and cosmetic manufacturers to disclose their records during an inspection. In 1953, Congress enacted the present factory inspection provision of the FD&C Act -- Section 704(a) -- granting FDA its current inspection authority with respect to food and cosmetic manufacturers.[9] Although FDA had sought statutory authority to inspect all pertinent records relating to food and cosmetic production, Congress withheld such authority from the Agency.

A press release issued by the Agency on August 27, 1953 (copy attached) explicitly acknowledged this lack of authority. The press release quoted the Commissioner of Food and Drugs as stating: "'The legislative history indicates Congress did not intend to include prescription files, formula files, complaint files, and personnel files within the scope of required inspections. FDA interprets this to mean that inspection of these records will be on a voluntary basis.'" Thus, the Agency's contemporaneous interpretation of Section 704(a) acknowledged Congress's refusal to grant records inspection authority.

Since 1953, Congress has amended Section 704(a) to grant records inspection authority for prescription drugs, restricted devices, infant formula, and nonprescription drugs, but has continued to deny the Agency authority to inspect records relating to all regulated products generally or to food and cosmetics in particular. These amendments demonstrate that Congress was aware that the review of records is outside the scope of the general inspection authority provided under the Act.

FDA has gone before Congress several times since the original enactment of Section 704 seeking expanded inspection authority under the Act. In making these appeals, the Agency consistently has maintained that it lacks the statutory authority to inspect food and cosmetic records. After evaluating the arguments put forth by FDA and industry representatives, Congress has repeatedly determined that the requested authority is unnecessary and inappropriate.

Under well-settled principles of administrative law, the Agency's contemporaneous and longstanding interpretation of a provision of the FD&C is presumed correct.[10] FDA bears a heavy burden to justify the reversal of its longstanding position, held

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[9] In 1952, the original version of Section 704 of the FD&C Act was struck down as unconstitutionally vague by the United States Supreme Court. *United States v. Cardiff*, 344 U.S. 174 (1952).

[10] *E.g., Atchison, T.&S.F.R. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 807 (1973) (an agency's settled policy "embodies the agency's informed judgement that, by pursuing that course, it will carry out the policies committed to it by Congress... [and] that those policies will be carried out best if the settled rule is adhered to."); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (weight given to rulings, interpretations and opinions of an agency depends upon "the (continued...)

since the enactment of section 704 in 1953, that it lacks records inspection authority for foods and cosmetics.[11] Rather than meeting this burden, FDA makes no attempt to explain its revised interpretation of the FD&C Act. Indeed, the preamble to the proposed and final regulation makes no reference to the Agency's repeated statements before Congress and others that FDA has no records inspection authority in the food and cosmetic areas.

The Agency's unjustified reversal of its longstanding position is particularly egregious in the instant case, where FDA has repeatedly told Congress that it lacks the authority to inspect food and cosmetic records. Over the past five decades, Congress has relied on this testimony in making its legislative determinations relating to the Agency. FDA cannot now usurp Congress's power by attempting to reinterpret the statute at this late date.

A. The 1962 Hearings Relating To The Drug Industry Act Of 1962.

In a hearing before the House Committee on Interstate and Foreign Commerce relating to the Drug Industry Act of 1962, Abraham Ribicoff, the Secretary of the Department of Health, Education, and Welfare, and George Larrick, the Commissioner of Food and Drugs, testified regarding the scope of the inspection authority provided under Section 704(a).[12] This testimony and the FDA's written statements unequivocally demonstrate the Agency's understanding that the general factory inspection provisions of Section 704(a) exclude access to records. An exchange between the Chairman of the Committee and Secretary Ribicoff illustrates this point:

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thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade"); *Shapiro v. United States*, 335 U.S. 1, 12 (1948) (contemporaneous administrative interpretation of a statute is highly relevant and material evidence entitled to serious consideration).

[11] *E.g., Motor Vehicle Manufacturers Association v. State Farm Mutual Insurance*, 463 U.S. 29, 48-49 (1983) (when departing from a settled policy, an agency must explain both the basis for its decision and the basis for reversing its previous policy); *Local 777, * * * AFL-CIO v. National Labor Relations Board*, 603 F.2d 862 (D.C. Cir. 1979) (when... [an agency] announces no principled reason for such a reversal, its action is arbitrary and the courts should be quick to so declare."); *General Electric Co. v. Gilbert,* 429 U.S. 125, 142-43 (1976) (assigning little weight to an agency's statutory interpretation which "flatly contradict[ed]" the position previously articulated by the agency); *Madison Galleries, Ltd. v. United States,* 870 F.2d 627, 631 (Fed. Cir. 1989) ("an agency interpretation which conflicts with the same agency's earlier interpretation is entitled to considerably less deference than a consistently held agency view"), citing *INS v. Cardoza-Fonseca*, 480 U.S. 421, 447 n. 30 (1987); *Seldovia Native Assoc., Inc. v. Lujan*, 904 F.2d 1335 (9th Cir. 1990) ("when an agency reverses a prior policy or statutory interpretation, its most recent expression is accorded less deference than is ordinarily extended to agency determinations").

[12] "Drug Industry Act of 1962," *Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives,* 87th Cong., 2nd Sess. 60, 67-74 (1962).

The CHAIRMAN: ... In your statement, you say that you are required to establish and police safe tolerances for known poisons in our food supply.

You are required to approve new drugs and to certify antibiotics from the standpoint of safety and to some extent efficacy. That is under present law?

SECRETARY RIBICOFF: Yes.

The CHAIRMAN: In those fields, are you authorized to look at the complaint files?

SECRETARY RIBICOFF: We are not.

The CHAIRMAN: Are you authorized to look at the shipping records?

SECRETARY RIBICOFF: No sir.

The CHAIRMAN: Are you authorized to look at the formula files?

SECRETARY RIBICOFF: We are not.

The CHAIRMAN: Are you doing a good job in those fields, from your viewpoint?

SECRETARY RIBICOFF: I would say that we cannot do a good job with these restrictions.[13]

Shortly after this exchange, Commissioner Larrick added: "We can do a much more satisfactory job and a more efficient job in these areas that you refer to Mr. Chairman, if we do have the authority that we seek in this amendment."[14] The Commissioner went on to admit that "in spite of the limitation of the statute, the great bulk of American industry deals with us forthrightly and does not hesitate to give us [the] information [we need]" on a voluntary basis.[15] Ultimately, the expanded inspection authority sought by the Agency at that time was granted by Congress only with respect to prescription drugs.

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13 *Id.* at 72.

14 *Id.*

15 *Id* at 73.

B. The 1971 Hearings Relating To FDA Oversight/Food Inspection

In 1971, the Agency again sought expansion of its existing food inspection authority from Congress. In hearings before the Subcommittee on Public Health and Environment of the House Committee on Interstate and Foreign Commerce, Charles Edwards, the Commissioner of Food and Drugs, and Virgil Wodicka, the Director of the FDA Bureau of Foods, argued that the Agency's efforts to monitor the quality control systems of food manufacturers were hampered because the Agency lacked the authority to inspect records.[16] In his testimony, Dr. Wodicka explicitly acknowledged that Congress had repeatedly withheld the authority to inspect food records from the Agency:

> DR. WODICKA: Our inspection efforts have been almost entirely concentrated on the inspection of the plant and the operations in it, and have paid somewhat less attention to the controls of those operations exercised by the company.
>
> This is in part because the agency has a number of times asked for authority to require the companies to show quality control records and the Congress has never felt that this was a necessary authority.
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> As a consequence, we are able to look at these records only from those companies that will voluntarily show them.
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> I think the number of such companies is increasing, and we want to mount a training program to put our inspectors in a position to make more effective use of this kind of information when it is available.
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> MR. ROGERS: In other words, you are saying that the law presently is deficient in the authority you have to look at records for quality control?
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> DR. WODICKA: Yes, sir.[17]

C. The 1978 Hearings Relating To The Food Safety And Nutrition Amendments Of 1978

Seven years later, FDA again told Congress that it lacked records inspection authority for foods. In 1978, hearings were held before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce with respect to the

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16 "FDA Oversight - - Food Inspection," *Hearings Before the Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, House of Representatives,* 92nd Cong., 1st Sess. 130-131 (1971).

17 *Id.* at 130.

Food Safety and Nutrition Amendments of 1978.[18] On numerous occasions during these hearings, FDA officials specifically commented on the Agency's lack of authority to review records during its inspections of food establishments.

1. Comments of the Department of Health, Education, and Welfare

Julius Richmond, the Assistant Secretary for Health, submitted comments reflecting "the general policy views of the Department" as an appendix to his prepared statement before the Subcommittee.[19] The comments referenced the limitations on the Agency's inspection authority several times, arguing that "[E]nforcement of the current law with respect to food is hampered by the limitations on FDA's authority and by the absence of provisions that would make it easier for the Agency to become aware of, and pursue violations of law."[20] The comments argued that a more expansive inspection authority was necessary for the efficient enforcement of the Act:

> FDA's ability to enforce the food laws is most hampered by the Agency's relatively narrow inspection authority. Enforcement of the food laws is made difficult because FDA is not able to insist on access to manufacturer's records. The lack of access to records inhibits enforcement because some violations of the law, for example, those related to the use of ingredients, can only be discovered by reviewing records. In other cases, proof of violations would be simplified if records could be reviewed. FDA's inspection authority should be expanded to provide for access to records bearing on whether a food is adulterated or misbranded as found in H.R. 10358 (Rogers).[21]

Despite specific consideration of these concerns, however, Congress refused to extend the Agency's inspection authority to include access to food records. Having failed repeatedly in its efforts to obtain records inspection authority through legislation, FDA cannot now accomplish by regulation that which Congress has specifically denied by statute.

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18 "Food Safety and Nutrition Amendments of 1978," *Hearings Before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, House of Representatives*, 95th Cong., 2nd Sess. (1978).

19 *Id.* at 119-131.

20 *Id.* at 125.

21 *Id.* at 128-129.

2. Statement of the FDA Chief Counsel

FDA's Chief Counsel, Richard Cooper, also focussed on the Agency's lack of records inspection authority in his statement before the Subcommittee. Referencing the Agency's limited enforcement authority, Mr. Cooper testified:

> Finally, to assist in the discovery of violations, H.R. 10358 would expand FDA's inspection authority.
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> . . . I believe it is quite important that the Food and Drug Administration be able to inspect the records that bear on possible adulteration or misbranding, that bear on ingredients that go into food, so that we can determine from the records where we cannot always determine from laboratory analysis what ingredients were put into the food, whether unapproved food additives are being used, and the like.[22]

Mr. Cooper's prepared statement to the Subcommittee emphasized the restrictions on FDA's inspection authority under the Act:

> Under current law, food processors are not required to permit FDA to inspect food processing records that may bear on whether products are adulterated or misbranded. FDA's ability to enforce the law is impaired by this limitation on its inspection authority because some violations of law (*e.g.*, those related to the use of ingredients) can be discovered most efficiently by reviewing records.[23]

Nonetheless, Congress did not grant the expanded inspection authority requested by FDA.

D. The 1978-1979 Hearings Relating To The Drug Regulation Reform Act of 1978/1979

In hearings before the House of Representatives and the Senate in 1978 and 1979 relating to the Drug Regulation Reform Act, FDA continued to seek expanded factory inspection authority under Section 704(a). FDA Commissioner Donald Kennedy sought increased inspection authority with respect to nonprescription drugs,[24] for which Section 704(a) at that time

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22 Id. at 310.

23 *Id.* at 315-316.

24 *E.g.*, "Drug Regulation Reform Act of 1979," *Hearings Before the Subcommittee on Health and Scientific Research of the Committee on Labor and Human Resources, United States Senate,* 96th Cong., 1st Sess. 361 (1979) ("We think enforcement provisions of the law should be made fairer and more effective by . . . expanding FDA's inspection authority, . . . so that FDA can better develop the facts needed to prove criminal and other violations when they occur."); (continued...)

provided the identical authority as food and cosmetics. In their testimony, FDA representatives adhered to the Agency's longstanding position that the general inspection authority of Section 704(a) does not extend to records inspection. They acknowledged that records inspection is authorized only where Congress has specifically granted FDA broadened authority, as with prescription drugs.

In his prepared statement to the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, Richard Cooper, FDA's Chief Counsel, noted that "under current law, FDA may inspect records relating to the manufacture of prescription drugs, but not records relating to over-the-counter drugs."[25] Testifying before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, the Secretary of Health, Education, and Welfare, Joseph Califano, explained that the proposed legislation "adds additional enforcement tools to present law."[26] Specifically, the Secretary explained that "the bill extends the factory inspection authority of the present act, which now permits inspection of records of prescription drug manufacturers, to reach records of nonprescription (OTC) drug manufacturers as well."[27]

E. The 1991 Hearings on the Food, Drug, Cosmetic , and Device Enforcement Amendments

Testimony by FDA officials, including FDA Commissioner Kessler, in 1991 reflects the Agency's continued recognition that it does not possess the statutory authority to require food manufacturers to disclose their records. In testimony before the Senate Committee on Labor and Human Resources in 1991, Commissioner Kessler stated that Congress and the Agency "need to look at enhancing our inspection authority, including records inspection."[28] Expanding on this point, Commissioner Kessler later stated:

> I have yet to see an agency get additional enforcement tools without assurances on the other hand. And I recognize that. But its's very hard, for example, to track down the maker of bogus apple juice or track down when oranges don't go into a factory but

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"Drug Regulation Reform Act of 1978, Part 2," *Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives*, 95th Cong., 2nd Sess. 1405 (1978) ("Our inspection authority would also be expanded so that we could reach records relating to possible violations involving over-the-counter drugs.").

25 "Drug Regulation Reform Act of 1978, Part 2," note 24 *supra*, at 1414.

26 "Drug Regulation Reform Act of 1978," *Hearings Before the Subcommittee on Health and Scientific Research of the Committee on Human Resources, United States Senate*, 95th Cong., 2nd Sess. 244 (1978).

27 *Id.*

28 "Role of Commissioner of Food and Drugs," *Hearing Before the Committee on Labor and Human Resources, United States Senate*, 102nd Cong., 1st Sess. 10 (1991).

> orange juice comes out at night and you can't go and inspect records, it really ties the hands of the field.[29]

In a hearing before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, Commissioner Kessler also explicitly acknowledged FDA's lack of records inspection authority under the Act. The bill under consideration would have amended Section 704(a) to broaden FDA's general inspection authority to include, among other things, the inspection of records.[30] Referencing a report by the Edwards Committee citing FDA's existing enforcement authorities, Congressman Dingell asked the Commissioner:

> Going down, with regard to foods, it says you have inspection authorities; you have none with regard to containers, commercial testing laboratories, photographs during inspection, record inspection, record copying. . . . . Is that not so?[31]

Commissioner Kessler agreed with this characterization of the Agency's food inspection authority, replying: "It certainly creates a serious problem."[32]

During this testimony, Commissioner Kessler was quite candid regarding the absence of statutory authority to conduct records inspections for food. Commissioner Kessler explicitly recognized that "[T]his legislation would provide the ability to inspect records in the food area, as we have in other areas.[33]

The 1991 legislation that would have expanded the Agency's inspection authority for foods and cosmetics was not passed by Congress. Thus, the Agency today remains as it has for over 40 years -- without records inspection authority for food and cosmetics.

F. The Food and Drug Administration Modernization Act of 1997

During Congressional consideration of the Food and Drug Administration Modernization Act of 1997 (FADAMA), the food, nonprescription drug, and cosmetic industries proposed that provisions be added to the legislation that would require national uniformity in the regulation of these product categories. FDA responded that it would object to such provisions unless the legislation also included records inspection. The nonprescription drug industry

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29 *Id.* at 21.

30 "Food, Drug, Cosmetic, and Device Enforcement Amendments," *Hearing Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives*, 102nd Cong., 1st Sess. 13-14 (1991).

31 *Id.* at 77.

32 *Id.*

33 *Id.* at 86.

accepted this trade-off, and FADAMA accordingly included both provisions.[34] The food industry abandoned its request for national uniformity rather than accept records inspection. The cosmetic industry continued its request for national uniformity without accepting records inspection and, after a lengthy Senate debate,[35] obtained a revised national uniformity provision.[36] Accordingly, FDA emerged from the most recent congressional consideration of this matter with another acknowledgement that it has no records inspection authority for food and cosmetics but no additional authority to inspect the records of food and cosmetic companies.

III. THE CASES CITED BY FDA IN SUPPORT OF PRIOR RECORDS INSPECTION PROPOSALS FAIL TO SUPPORT THE AGENCY'S RECENT ATTEMPT TO REINTERPRET THE STATUTE.

The preambles to the proposed and final regulations contain no legal analysis of the statutory authority on which FDA relies for inspection of food and cosmetic records. In a preamble to a prior proposed regulation, however, the Agency devoted substantial space to arguing that it possesses the legal authority to require the disclosure of food records.[37] In particular, the Agency contended that a few older court decisions support its new claim of authority. A review of these cases, however, demonstrates that they are not on point.

The Agency asserts that the 1973 Supreme Court decision in *Weinberger v. Bentex Pharmaceuticals, Inc.*[38] supports its contention that "FDA may require records to be maintained in specific instances and may inspect those required records, despite the act's lack of express, general statutory authority to inspect records."[39] In *Weinberger*, the Court reversed the lower court's holding that FDA lacked jurisdiction under the FD&C Act "to decide in an administrative proceeding what is a 'new drug' for which an NDA is required."[40] In the lower court's view, the judiciary had exclusive jurisdiction to make such determinations.[41] In

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34 Sections 412(a) and (b) of FADAMA, 111 Stat. 2296, 2374 (1997).

35 143 Cong. Rec. S8837 ff. (September 5, 1997), S8878 ff. (September 8, 1997), S9133 ff. (September 22, 1997) (daily eds.).

36 143 Cong. Rec. S9145 ff. (September 11, 1997) (daily ed.). Section 412(d) of FADAMA, 111 Stat. 2296, 2376 (1997).

37 61 Fed. Reg. 3885 (February 2, 1996) (FDA records inspection of nutrient descriptor and disease claims for food). Notably, the preamble did not address FDA's repeated testimony to Congress regarding its lack of inspection authority for food industry records.

38 412 U.S. 645 (1973).

39 61 Fed. Reg. at 3888.

40 412 U.S. at 648.

41 The lower court had concluded that the Drug Amendments of 1962 to the FD&C Act established two distinct forums for the regulation of drugs -- an administrative forum and a judicial forum. In the lower court's view, the FDA's role was limited to premarketing clearances for new drugs or withdrawal of previous drug approvals, while the judiciary had exclusive (continued...)

concluding that it could "discern no such jurisdictional line under the Act," the Supreme Court reasoned: "One function is not peculiar to judicial expertise, the other to administrative expertise. The two types of cases overlap and strongly suggest that Congress desired that the administrative agency make both kinds of determination."[42]

Weinberger thus rested on an analysis of congressional intent, and its finding of "implicit" authority under general principles governing the primary jurisdiction of administrative agencies has no application to the narrow issue of authority to inspect company records. After five decades of unsuccessful requests that Congress enact records inspection authority under the Act, no credible argument can made that Congress has always intended the Agency's inspection authority to reach food and cosmetic records. FDA's reliance on *Weinberger* to claim legal authority to implement the proposed regulation thus is in error.

National Confectioners Association v. Califano,[43] also cited by the Agency, similarly rests on the court's analysis of congressional intent. In *National Confectioners*, the United States Court of Appeals for the Tenth Circuit recognized that, as a legal matter, "the regulation must be consistent with Congressional intent and the substantive provisions of the whole statute."[44] Although the Tenth Circuit made the factual determination that the particular source coding and recordkeeping requirements under consideration were permissible, there are several reasons why this holding cannot be used to justify mandatory records inspection.

First, and most important, *National Confectioners* applied only to the requirement that food manufacturers make and keep records. It had nothing to say about FDA's authority to inspect those records. FDA did not assert that it could inspect food company records and the court did not so hold.[45]

Second, *National Confectioners* was decided in January 1978. Later that year, FDA made several statements before Congress acknowledging its lack of food records inspection authority under the Act. Since this decision, the Agency has continued to seek congressional authorization for records inspection for more than two decades. If the Agency's authority to inspect records was settled by *National Confectioners*, FDA surely would not have persisted in its testimony to Congress that its lack of records inspection authority in the food area hampers its

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jurisdiction to enforce the requirement that new drugs be cleared as safe and effective before marketing. *Id.* at 648-649.

42 *Id.* at 652.

43 569 F.2d 690 (D.C. Cir. 1978).

44 *Id.* at 695.

45 Even if the court had found records inspection authority in *National Confectioners*, this finding would have no bearing in the instant case. The regulation at issue in *National Confectioners* related to distribution records, not food records generally. Section 703 of the FD&C Act explicitly authorizes the Agency "to have access to and to copy all records showing the movement [of food] in interstate commerce." This statutory provision has no application to the records required to be presented for inspection under the export regulation.

enforcement efforts. Nor would Congress have continued to conduct hearings regarding the alleged need for such authority.

Third, *National* Confectioners explicitly rejects Section 701(a) as an independent source of authority not found elsewhere in the Act. Emphasizing the importance of congressional intent, the court stated: "Section 701(a) is not a license for expansion of the FDA's regulatory authority based on fanciful interpretations of the substantive portions of the Act."[46]

Finally, an application of the legal standard articulated in *National Confectioners* mandates a determination that FDA lacks the authority to impose the records inspection requirements of the proposed regulation. As the Tenth Circuit emphasized, a regulation must be consistent with congressional intent. In light of the overwhelming evidence that Congress intended to withhold records inspection authority from FDA in the food area, and the Agency's repeated historical acknowledgements that such authority has not been granted, the assertion that FDA may require food manufacturers to disclose records under the proposed regulation cannot be sustained.

The Agency also cites Toilet *Goods Association v. Gardner*[47] to support its broad assertion that "FDA may impose recordkeeping requirements where they effectuate the act's goals."[48] In *Toilet Goods*, however, the Supreme Court did not reach the ultimate issue of whether the FDA regulation was an impermissible exercise of authority.[49] Rather, as every student of Administrative Law knows, the Court held that the Toilet Goods Association's challenge to the regulation was not ripe for judicial reviews.[50]

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46 *Id.* at 695.

47 387 U.S. 158 (1967).

48 61 Fed. Reg. at 3888.

49 The regulation, promulgated to implement the Color Additive Amendments of 1960, provided that FDA could suspend a certification for batches of color additives if a person refused to provide the Agency with free access to "all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived." 387 U.S. at 161.

50 *Id.* at 160-161.

IV. CONGRESS'S REFUSAL TO GRANT RECORDS INSPECTION AUTHORITY TO FDA REFLECTS A REASONED DETERMINATION THAT SUCH AUTHORITY IS UNNECESSARY FOR THE EFFECTIVE ENFORCEMENT OF THE FD&C ACT.

A. Congress Has Determined That The Agency's Enforcement Authority Is Sufficiently Expansive Without Records Inspection Authority.

Congress's continued refusal to provide FDA with records inspection authority for food and cosmetics has been reasonable and principled. In response to the Agency's efforts to obtain such authority, the food and cosmetics industries have raised serious concerns regarding the disclosure of records during a warrantless FDA inspection.[51] Indeed, granting FDA inspectors the authority to review company records without a search warrant and without a showing of probable cause to believe there has been a violation of law raises serious constitutional issues.

The constitutional issues raised by such unchecked executive authority are particularly grave in light of the criminal liability imposed on manufacturers under the FD&C Act. Any violations discovered during an inspection could be used by the Agency in a prosecution under the FD&C Act's "strict liability" criminal standard. The Supreme Court has held on two occasions that an individual is subject to criminal sanctions, including imprisonment, for any violation of the Act, regardless of knowledge or intent.[52] Subjecting an individual to criminal prosecution without a showing of knowledge or intent is a rare and particularly harsh government action. As industry representatives have testified to Congress, the severity of these criminal consequences render the constitutional issues even more compelling and provide a powerful argument against expanding the Agency's inspection authority any further.

Moreover, Congress has recognized that providing Agency access to food and cosmetic records could compromise the trade secrets of industry members. Congressman Hastert articulated this concern during an exchange with Commissioner Kessler in the 1991 Hearings on the Food, Drug, Cosmetic, and Device Enforcement Amendments:

> MR. HASTERT: . . . The records should be considered the private property of a business. To have people swoop in and take all the records and information that a company has kept to help create a quality product, you all of a sudden create a disincentive to keep records at all. There is a great liability out there.

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51 *E.g.*, "Food, Drug, Cosmetic, and Device Enforcement Amendments," *Hearing Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives*, 102d Cong., 1st Sess. 154-167, 168-184, 259-271 (1991).

52 *United States v. Dotterweich*, 320 U.S. 277 (1944); *United States v. Park*, 421 U.S. 658 (1975).

. . . .

> MR. HASTERT: . . . What would prevent somebody from your Agency from coming in, learning the [Coca-Cola] formula, or a formula like that, for instance, that is proprietary information and then several years later, once he has that information and is not in your employ any more, going out and exploiting it?
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> MR. KESSLER: You could go to jail, sir.
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> MR. HASTERT: Even if the individual does go to jail, the secret is already disclosed.
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> MR. KESSLER: No question, you are correct, sir, but there are very severe criminal penalties for disclosure of trade secrets, but there is that risk.
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> MR. HASTERT: People take those risks all the time.[53]

Congress's determination that FDA's inspection authority for food and cosmetics should not be expanded to include the review of records thus rests on a reasoned evaluation of the issue, informed by the testimony of both the Agency and the industry.

B. For Almost A Century, The Agency Has Effectively Implemented The Food And Drug Laws Without Records Inspection Authority.

Since 1906, the Agency has effectively implemented the statute without records inspection authority for foods, and since 1938 it has done so for cosmetics. The FD&C Act provides FDA with extraordinarily broad enforcement powers, ranging from informal regulatory action for minor offenses to formal court action for major offenses. In sharp contrast to most government investigators, FDA inspectors may gain entry to establishments with no advance notice, no warrant, and no special permission from the owner or operator of the establishment. Refusal to permit an FDA inspection is a criminal offense.

The Agency consistently and effectively has used these statutory powers to implement the FD&C Act. Congress thus has found no need to increase FDA's already expansive powers to authorize records inspections for food and cosmetic establishments.

C. Enforcement Concerns Cited By The Agency Have Been Considered And Rejected By Congress When It Refused To Grant Records Inspection Authority In The Past.

The export regulation presents no unique issues of law or fact to distinguish it from the cases in which records inspection authority has been requested and denied by Congress

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53 "Food, Drug, Cosmetic, and Device Enforcement Amendments," note 51, *supra*, at 87.

in the past. In the context of enforcement, there is nothing to differentiate compliance with foreign law under Section 801(e)(1) of the FD&C Act from any of the other food or cosmetic provisions of the Act. If records inspection could be justified here, it could be equally justified for all other food and cosmetic issues over which FDA has jurisdiction. But FDA has already acknowledged that it has no records inspection authority in these other areas.

Thus, the enforcement concerns raised by the Agency already have been considered by Congress. Ultimately, these concerns were not sufficient to persuade Congress to grant the Agency records inspection authority for food and cosmetics.